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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/759,870 | 01/16/2004 | Luigi Silvestri | 8707-2171 | 8421 |

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| EXAMINER | |
|---|---|
| GEDEON, BRIAN T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/759,870 | SILVESTRI ET AL. | |
| | Examiner | Art Unit | |
| | Brian T. Gedeon | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

Claim 2 is rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite. It is indefinite if "said shape parameter" is referring to the "shape characteristic" recited in claim 1. Appropriate clarification is requested.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juran et al. (US Patent no. 6,016,447) in view of Wahlstrand et al. (US Patent no.

5,534,018), Baker, Jr. et al. (US Patent no. 4,964,407), and Mills (US Patent no. 4,532,931).

In regards to claim 1, Juran et al. discloses a pacemaker with a pulse generator 10 and a connector head 11 enclosed in a canister or case. The generator 10 has a stimulation/pacing circuit 26 with a lead interface circuit 19 serving as terminals for connecting stimulation probes/leads 14. The implant detect circuit 46 is used as a discriminating means that functions to automatically determine when pulse generator is implanted within a patient, and to provide and indication of this event, column 9 lines 58-64, and to determine that the leads are connected and to see what the configuration of the lead is, column 12 lines 55-57. Further, the implant detect circuit 46, can initiate a program to store values, such as those of pulse width and amplitude, column 16 lines 63-67 and probe polarity. A central processing unit 32 is used to control the operating programs and parameters of the implantable device.

Regarding the generator comprised of switches to control the selective stimulation modes of the device. Baker, Jr. et al. describes a pacemaker 38 that can be connected to ground 30 by switch 40. Further, switches 34, 40, and 44 can be programmed to open and close depending on whether bipolar or unipolar stimulation is chosen, column 4 lines 19-23.

Regarding the detecting of and analyzation of one pulse signal, Baker, Jr. et al. uses a sensing amplifier 16 for sensing the test pulse and any attenuation of that pulse due to the impedance characteristic of the presence or absence of the probe, column 4 lines 52-67.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine references to create a circuit of an implantable cardiac device that detects the presence of or absence of a pacing probe, and detect if the device has been properly implanted.

Regarding the metallic case, Mills teaches that the housing known as the "case" is preferably made of a suitable metal, column 4 lines 64-66.

In regards to claim 2, Baker, Jr. et al. teaches that the test signal can be selected from a variety of test signals, including square waves, column 4 lines 52-54.

In regards to claims 3 and 7, Juran et al. describes the device as claimed including the lead interface 19 capable of connecting bipolar probes with tip and ring electrodes, column 7 lines 57-58. However, Juran et al. does not demonstrate the use of switches controlled to output the proper stimulation mode. Baker, Jr. et al. describes a pacemaker that uses switches 34, 40, 44 that when opened or closed can be used as a means for selectively producing either a bipolar stimulation or monopolar stimulation, column 4 lines 19-23. Baker, Jr. et al. states that a parallel switch 40 connected to a capacitor 42 that can be controlled to connect the system to ground. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to make use of switches in order to control whether the device is used as a bipolar or monopolar stimulator, as well as controlling the connection to the reference.

In regards to claim 4, Juran et al. substantially describes the invention as claimed with the discrimination means, except the use of the metallic case as a reference for measuring the desired signal parameter. Wahlstrand et al. teaches that the conductive

hermetic canister 11 that functions as the case, serves as an indifferent electrode, column 6 lines 44-46. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made since it was known in the art that the implantable metallic case can be used a reference electrode for taking signal measurements.

In regards to claims 5,6,8-10,12-14 and 16-18, the pacemaker of Juran et al. uses implant detect circuitry 46 to measure certain parameters, such as impedance, in order to determine the presence or absence of a stimulating probe, column 11 lines 14-24. The parameter measured is periodically referenced to a threshold value to determine that the leads are connected, column 12 lines 55-61. The device also allows for the probe polarity to be configured, column 13 lines 12-13. Since the pulse width corresponds to changes in the potential at the terminals, and the change in potential depends on the impedance seen at the terminals of the device, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the pulse at the terminals and compare that value with a threshold in order to determine if a probe has been connected and if that probe is either monopolar or bipolar.

In regards to claims 11 and 15, Juran et al. substantially describes the claimed device including the lead terminal interface 19, which can establish the necessary connection for the various conductors in a probe, such the tip and ring electrodes in a bipolar probe, column 7 lines 54-58. However, Juran et al. does not disclose the method of selective stimulation for either a unipolar case or a bipolar case by means of switches. Baker et al. shows a pacemaker device with switch that are programmed to

control the connection to ground and the desired stimulation modes, column 3 lines 65-67 and column 4 lines 19-23. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize switches in the circuitry in order to control the proper stimulation signal output to the designated probes connected to the generator.

In regards to claim 19, the pacemaker described by Juran et al. is capable of selectively operating in any of a plurality of operational models, column 10 lines 35-39. Juran et al.'s device also has a preliminary set of program instructions to be run during pre-implantation; this mode runs instructions to detect implantation and probe connection, column 12 lines 26-35. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include at set of preliminary program instructions to operate as a safety mode before and during implantation so that improper stimulation patterns are not delivered to the patient.

In regards to claim 20, the pacemaker described by Juran et al. uses a central processing unit 32 as its main control circuit. Further, the use on an activity sensor 40 and other sensor could be employed as well, column 9 lines 26-27. The implant detect circuit 46 can be used to store data and generate a date that is stored in the device to serve as the warranty date, column 17 lines 3-5. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a control circuit so that the implantable device can be activated in the proper functional mode and to initialize the function of other algorithms and sensors present in the device.

In regards to claim 21, the pacemaker described by Juran et al. takes parameter measurements that indicate a failing bipolar lead may cause an automatic switch to unipolar configuration, column 13 lines 21-23. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include at set of preliminary program instructions to operate as a safety mode before and during implantation so that improper stimulation patterns are not delivered to the patient.

In regards to claim 22, the pacemaker described by Juran et al. states that preferably when the device established unipolarity, the polarity would remain unipolar and not revert to bipolarity, column 13 lines 28-32. This statement anticipates that when the device establishes bipolarity, the same will occur. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a safety means to ensure that an improper stimulation mode does not get sent to the connected probes.

## ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references pertain to implantable cardiac devise equipped to sense lead polarity and degradation problems: Hansen et al. (US Patent no. 5,431,692) discloses a method and apparatus for testing compatibility of lead polarity and polarity programming of a cardiac stimulator; Weinberg et al. (US Patent no. 5,476,485) discloses an automatic implantable pulse generator; Schmukler (US Patent no. 5,571,156) discloses a device to detect switched implantable electrical

stimulator leads; McVenes et al. (US Patent no. 5,741,311) discloses an implantable medical device system with method for determining lead condition; and Jorgenson et al. (US Patent no. 6,317,633) discloses an implantable lead functional status monitor and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG